K071505

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510(k) SUMMARY

Submitter's Name and Address:

Integra NeuroSciences
311 Enterprise Drive
Plainsboro, NJ 08536
609-275-0500 (Telephone)
609-275-9445 (Fax)

AUG - 6 2007

Contact Person and Telephone Number:

Jon Caparotta, RAC
Director Regulatory Affairs
Integra LifeSciences Corporation
609-936-2495

Date Summary was Prepared: July 24, 2007

Name of the Device:

Trade Name:	NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System
Common Name:	Neurological Diagnostic Device
Classification Name:	Intracranial Pressure Monitoring Device, 21 CFR 882.1620, Product Code GWM
Classification Panel:	Neurology Device Panel

Substantial Equivalence:

The modified NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System is substantially equivalent in function and intended use to the NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System previously cleared under 510(k) K050720 on 5/11/05.

Testing was performed by Integra NeuroSciences, San Diego, CA, Integra NeuroSciences, Andover,UK and GemSoft, Inc in accordance with Integra established test protocols utilizing the following guidelines and standards:

- *FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005*
- *FDA Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices, September 9, 1999*
- *General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002*
- *AAMI TIR32:2004, Medical Device Software Risk Management*
- *IEC 601.1, General Requirements for Safety Medical Electrical Equipment (in process and to be completed prior to market release)*

The result of software testing indicates the System Requirements Specifications and System Functional Specifications have been fully met and that the NeuroSensor System

is safe for use as a cerebral blood flow and intracranial pressure monitoring system in monitoring cerebral blood flow in patients at risk of cerebral ischemia, and for the direct monitoring of intracranial pressure in intraparenchymal applications.

System testing was performed in accordance with established protocols to confirm the NeuroSensor System requirements as outlined in the product's functional specification met the product's defined requirements. These tests included verification and validation of the following System operations:

- Screen Administrative Functions
- Data Integrity, Display and Storage
- Mechanical and Electrical Functionality
- Instructional and Informational Content

Device Description:

The NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System consists of a single-use parenchymal probe for the real-time measurement of cerebral blood flow (CBF) and intracranial pressure (ICP) and a monitor for the display and storage of these measured variables and the computation and display of derived variables.

Indications for Use:

The NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System is intended for use by a qualified clinician in monitoring cerebral blood flow in patients at risk of cerebral ischemia, and for the direct monitoring of intracranial pressure in intraparenchymal applications.

Technological Characteristics:

The NeuroSensor® System consists of a single-use probe and introducer for the continuous real-time measurement of Cerebral Blood Flow (CBF) and Intracranial Pressure (ICP), and a monitor for the display and storage of these measured parameters and the computation and display of derived parameters.

Two transducers are located at the tip of the probe. The CBF transducer consists of two optical fibers and functions by the principles of laser doppler flowmetry. The ICP sensor is a MEMS (Micro-Electro Mechanical System) silicon strain gauge. The probe is designed for use with the NeuroSensor® Model NS-100 monitor. A "cranial bolt" introducer is included with each probe. The cranial bolt is inserted in a twist drill hole in the skull. The probe is inserted into brain and is held in position by the cranial bolt.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2007

Integra Lifesciences Corporation
% Mr. Jon Caparotta
Director Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K071505
Trade/Device Name: NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System
Regulation Number: 21 CFR 882.1620
Regulation Name: Intracranial pressure monitoring device
Regulatory Class: II
Product Code: GWM
Dated: July 19, 2007
Received: July 20, 2007

Dear Mr. Caparotta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071505

INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name: NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System

Indications for Use:

NeuroSensor® Cerebral Blood Flow and Intracranial Pressure Monitoring System, is intended for use by a qualified clinician in monitoring cerebral blood flow in patients at risk of cerebral ischemia, and for the direct monitoring of intracranial pressure in intraparenchymal applications.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter-Use**_____ (Part 21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071505